K011386

AUG - 3 2001

510(k) Summary

This 510(k) Summary for the EBI OsteoStim™ Granules - Resorbable Bone Graft Substitute is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** Jon Caparotta, RAC
Manager Regulatory Affairs
EBI, L.P.
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Parsippany, NJ 07054

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Date prepared: May 3, 2001

2. **Proprietary Name:** EBI OsteoStim™ Granules - Resorbable Bone Graft Substitute
Common Name: Bone Graft Substitute, Bone Void Filler
Classification Name/Code: MQV

3. **Predicate or legally marketed devices that are substantially equivalent:**

- Interpore Intl. Pro Osteon® 500R Bone Graft Substitutes
- Orthovita, Inc. Vitoss™ Scaffold Synthetic Cancellous Bone Void Filler
- Wright Medical Technology, Inc. Osteoset® Pellets – Bone Void Filler

4. **Device Description:** EBI OsteoStim™ Granules – Resorbable Bone Graft Substitute is a morselized calcium sodium phosphate bone graft material for the repair of bony defects. The material consists of osteoconductive and bioresorbable granules approximately 1-4 mm in size, provided sterile. When placed in contact with viable bone, new bone forms on and between EBI OsteoStim Granules.

When packed into a bony site, EBI OsteoStim Granules initially occupy approximately 30% of the defect volume, leaving 70% void volume for bone ingrowth. During the bone healing process, EBI OsteoStim Granules are gradually resorbed and replaced by bone and connective tissues by cellular remodeling.

5. **Intended Use:** EBI OsteoStim™ Granules - Resorbable Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. EBI OsteoStim Granules are indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. EBI OsteoStim Granules provide a bone graft substitute that resorbs and is replaced with bone during the healing process.

6. **Comparison to the Predicate Device:** There are no significant differences between EBI OsteoStim™ Granules – Resorbable Bone Graft Substitute and the Pro Osteon® 500R Bone Graft Substitute. The EBI OsteoStim Granules – Resorbable Bone Graft Substitute and the Pro Osteon 500R Resorbable Bone Graft Substitute are technically and functionally very similar. The EBI OsteoStim Granules – Resorbable Bone Graft Substitute is substantially equivalent* to the predicate device in regards to intended use, material and function.

- Both materials are composed of calcium salts that are biocompatible and bioresorbable. EBI OsteoStim Granules are composed of calcium sodium phosphate. The predicate is composed of calcium carbonate and hydroxyapatite.
- Both materials have been shown to allow significant bone formation and simultaneous resorption of implanted material during the healing of bony voids within 24 weeks in vivo. By 48 weeks, bones with healed defects grafted with EBI OsteoStim exhibited biomechanical integrity similar to intact bones and substantial resorption of implanted graft material.
- The morphology of the jagged, irregularly shaped EBI OsteoStim Granules differs from the porous granules of the predicate. However, the volume fraction occupied by both materials in a packed defect is very similar.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2001

Mr. Jon Caparotta, RAC
Manager regulatory Affairs
EBI, L.P.
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K011386
Trade/Device Name: EBI OsteoStim™ Granules –Resorbable Bone Graft Substitute
Regulatory Class: Unclassified
Product Code: MQV
Dated: May 4, 2001
Received: May 7, 2001

Dear Mr. Caparotta:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if known): K011386

Device Name: **EBI OsteoStim™ Granules - Resorbable Bone Graft Substitute**

Indications For Use:

EBI OsteoStim™ Granules - Resorbable Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. EBI OsteoStim Granules are indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. EBI OsteoStim Granules provide a bone graft substitute that resorbs and is replaced with bone during the healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

D Mitchell MD for CAW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011386